

April 4, 2005  
Gary M. Jackson  
Assistant Administrator for Size Standards  
Office of Size Standards  
Small Business Administration  
409 Third Street, SW  
Washington, DC 20416



APT Pharmaceuticals Inc.  
101 N. Wilmot Rd., Suite 600  
Tucson, AZ 85711-3365

**Re: Proposed Rulemaking Affecting SBIR Funding**

Dear Mr. Jackson:

On behalf of APT Pharmaceuticals Inc., I want to thank you for the opportunity to comment on the Small Business Administration's (SBA) Advance Notice of Proposed Rulemaking (ANPRM) regarding the participation of businesses in the SBIR program that are majority-owned by one or more venture capital companies (VCC).

APT Pharmaceuticals typifies the small business that the SBIR program was created to help, a small business working to commercialize new technologies in biotechnology. Companies such as ours normally receive SBIR grants to fuel the research and development that lead to the commercialization of a technology. Along with future SBIR funding, our company hopes to receive additional crucial financial support from venture capital firms and other similarly situated entities. Without such financial support it is unlikely our technology would be fully commercialized. It is for this reason I believe it is vital that small businesses such as ours be allowed to participate in the SBIR grant program.

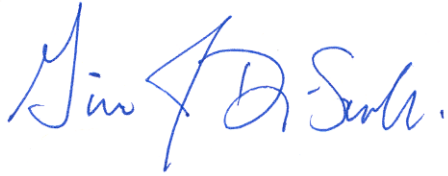
APT Pharmaceuticals has committed significant resources to develop and commercialize a steroid alternative for treating a variety of inflammatory diseases with inhaled dosage forms of the anti-inflammatory agent hydroxychloroquine (HCQ). APT is initially developing proprietary aerosolized HCQ (AHCQ) formulations for asthma and allergic rhinitis.

We understand the 51% Rule now allows an SBIR award recipient to be owned by a VCC, as long as the VCC is itself owned and controlled by U.S. individuals. APT Pharmaceuticals has received funds, and expects to receive further funds, from VCCs that are not, in fact, owned or controlled by U.S. individuals. Some of these VCCs are, or could be owned by, a nonprofit entity such as a university or research institution. These entities may differ in structure or ownership from typical VCCs; however, they have similar objectives of encouraging product development by small companies. Additionally, most, if not all, nonprofit VCCs often make investments to advance the objectives of the Bayh-Dole Act. We firmly believe that companies in which nonprofit VCCs invest should be able to participate in the SBIR grant program. **Thus, we believe that the SBA should (1) provide an exclusion from affiliation with VCCs in**

**determining small business eligibility and (2) include nonprofit related VCC entities within the scope of the definition of VCC considered by the SBA in its rule making.**

I appreciate the opportunity to comment on this important matter.

Sincerely,

A handwritten signature in blue ink, reading "Gino Di Sciullo". The signature is fluid and cursive, with the first name "Gino" and last name "Di Sciullo" clearly legible.

Gino Di Sciullo, Ph.D.  
President  
APT Pharmaceuticals Inc.